

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

MEMORANDUM

DATE: February 26, 2019

SUBJECT: Review of Storage Stability and Corrosion Characteristic Study for

FireWorxx 80, an End-Use Product Containing 44% Caprylic Acid

and 36% Capric Acid as Active Ingredients

DP Barcode: 449162 Decision №: 544631 Submission №: 1025283 MRID: 506870-01 EPA Reg. №: 67702-54 Chemical Class: Biochemical

Active Ingredients: Caprylic Acid Capric Acid PC Code: 128919 128955 CAS RN: 124-07-2 334-48-5

Type of Review: Product Chemistry

FROM: Kathleen Martin, M.S.E.S., Chemist

Risk Assessment Branch

Biopesticides and Pollution Prevention Division

THROUGH: Russell S. Jones, Ph.D., Senior Scientist

Risk Assessment Branch

Biopesticides and Pollution Prevention Division

TO: James Parker, Risk Manager

Biochemical Products Branch

Biopesticides and Pollution Prevention Division

ACTION REQUESTED. Review the Storage Stability (OPPTS 830.6317) and Corrosion Characteristics (OPPTS 830.6320) study submitted by W. Neudorff GmbH KG in fulfillment of a term of registration of the end-use product, FireWorxx 80 (EPA Reg. № 67702-54) on August 24, 2018.

KATHLEE Digitally signed by KATHLEEN MARTIN Date: 2019.04.09

Russell S.

Jones, Ph.D. Date: 2019.03.18

Digitally signed by Russell S. Jones, Ph.D.

SUMMARY. Overall, the study is UNACCEPTABLE because it fails to demonstrate that FireWorxx 80 is compatible with its packaging. Please see the attached Data Evaluation Record for the study review. While the study does not satisfy the Corrosion Characteristics data requirement (OPPTS 830.6320), it does satisfy the Storage Stability requirement (OPPTS 830.6317).

DATA EVALUATION RECORD

KATHLEE Digitally signed by KATHLEEN MARTIN Date: 2019.04.09

Reviewed by: Kathleen Martin, M.S.E.S. N MARTIN Date: 2019-04-09 Secondary by: Russ Jones, Ph.D. Ph

S. Jones, Date: 2019.03.18
Aug Secondary by: Russ Jones, Ph.D.
Ph.

Russell Digitally signed by Russell S.

Type of Study: Storage Stability and Corrosion Characteristics (OPPTS 830.6317 and 830.6320)

MRID: 506870-01
DP Barcode: 449162
Decision №: 544631

Sponsor: W. Neudorff GmbH KG

An der Muhle 3 Emmerthal, 31860

Germany

Report Title: FireWorxx 80: Storage Stability and Corrosion Characteristics

Author: William Gravelle, M.S.
Study Completed: September 13, 2018
Testing Facility: Product Safety Labs

Study ID: 44664

Confidentiality: No claim of confidentiality

Good Laboratory

With a few exceptions, the study was conducted under 40 CFR 160

Practice (GLP):

Test Material: FireWorxx 80, Lot Number PG8-177-1

Classification: UNACCEPTABLE

METHOD

FireWorxx 80 is an end-use product containing 44% caprylic acid and 36% capric acid as active ingredients; it is packaged in plastic containers. To evaluate its storage stability and corrosion characteristics, Product Safety Labs (PSL) conducted a one-year combined study. Parameters considered in the study include: concentration of active ingredients; physical appearance of the product (e.g., color changes, clumping); physical appearance of the container (e.g., cracking, fogging, discoloration); and, container weight.

To initiate the study, two aliquots were prepared by placing test material in translucent, 250 mL, high-density polyethylene (HDPE) bottles. Observations were made at 0, 3, 6, 9, and 12 months; samples were stored at 16.2 to 27.1°C (61 to 81°F). The concentration of active ingredients was quantified using high performance liquid chromatography (HPLC) with a photometric diode array detector (PDA); method performance (e.g., linearity, precision) was performed under PSL Study 44663. More information on the analytical methods including HPLC operating conditions and chromatograms may be found in the study volume.

RESULTS

Concentration of the Active Ingredients. Table 1 shows the average concentrations at each time interval; Figures 1 and 2 show the same information graphically (the shaded areas indicate the certified limit ranges).

Appearance of the Test Product. The physical appearance (pale yellow liquid) of the product did not change over the duration of the study.

Appearance and Weight of the Container. The only significant finding was in the appearance of the container. After being stored for three months, the containers became "severely

Table 1 Concentration of Active Ingredients

Time (months)	Concentration (%)	
	Caprylic Acid	Capric Acid
0	43.68	36.75
3	43.04	36.39
6	43.35	36.32
9	43.76	36.20
12	42.25	35.86

distorted exhibiting a concave, or 'squeezed-in' in appearance;" this remained for the duration of the study. Study investigators suggested that this distortion may be due to "reduction of gas in the container headspace." Over the 12-month study period, the weight of the container (with sample) decreased less than 0.2 percent.

Figure 1 Concentration of Caprylic Acid

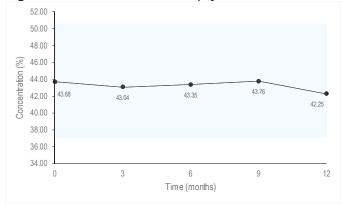
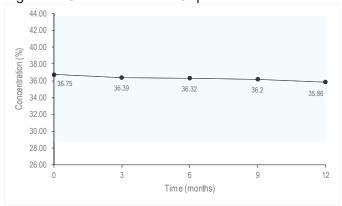


Figure 2 Concentration of Capric Acid



DISCUSSION AND CONCLUSION

Overall, EPA finds this study to be UNACCEPTABLE because it fails to demonstrate that FireWorxx 80 is compatible with its packaging. The objective of the Corrosion Characteristics Study is "to evaluate effects of the product formulation on the container. If the pesticide is highly corrosive, measures can be taken to ensure that lids, liners, seams or container sides will not be damaged and cause the contents to leak during storage, handling, or use" (OPPTS 830.6320). While no signs of leaking were observed, the Agency is concerned about the severe distortion reported by the study investigators as it suggests that FireWorxx 80 may be incompatible with its packaging. The distortion was seen in both samples, it occurred early in the study, and the containers never returned to their native shapes.

While the Corrosion Characteristics data requirement (OPPTS 830.6320) is not satisfied by this study, the Storage Stability (OPPTS 830.6317) requirement is. When stored from 61 to 81°F (16 to 27°C) for 12 months, the concentrations of caprylic and capric acids are well within the certified limits and thus, the product is considered to be stable. In conducting the study, PSL used appropriate analytical methods and conditions that mimic actual storage.